

Annex 7

Terms of Reference Post-Market Monitoring Sentinel Surveillance

PROJECT BACKGROUND AND OBJECTIVES

Properly functioning cold chain equipment (CCE) protects vaccine potency. **Post Market Monitoring (PMM)** refers to the collection and analysis of CCE performance data from health and storage facilities to enable corrective and preventive action leading to improved CCE performance.

PMM aims to track CCE performance data to inform and improve vaccine management at the country level. When reported to the WHO Product Quality and Safety Team (PQS) the performance data informs specifications and verification protocols (test procedures) as well as helping to provide timely performance feedback to manufacturers and countries to enable corrective and preventative actions leading to improved CCE performance.

The recommended method of collecting CCE performance data is via a sentinel surveillance system managed by an in-country Sentinel Surveillance Officer. Key characteristics include:

- A sentinel surveillance system is used when detailed high-quality data are needed that cannot be obtained through a passive system;
- Such a system can be a rapid and economical surveillance method;
- Data collected in country, through a well-designed sentinel system, can be used to signal trends, identify breakdowns/performance issues etc and through follow up identify root causes and provide timely feedback into corrective actions by manufacturers and EPI programmes (including HCW training) and preventative actions through specification modification;
- A designated group of reporting sources; agreement with designated health system staff to report on a set of health facility performance metrics on a regular basis (including zero reporting);
- Deliberately involves only a limited network of carefully selected reporting sites;
- Dependent on the readiness of participating sites, including the knowledge of staff, capacity to report accurately and willingness to be trained.

SCOPE OF WORK AND DELIVERABLES:

[Implementer], with support from WHO PQS, will build on existing systems to establish sentinel sites and set up a sustainable monitoring system for CCE performance. Activities include, but are not limited to:

Setting up a Surveillance System:

- If the implementer is outside the national program, establish an agreement with the national EPI program for the setting up of the sentinel surveillance sites and monitoring system, including agreement on the sites selected, indicators to be monitored, a work plan for surveillance activities and roles and responsibilities of designated government focal points;
- Leverage existing inventory, deployment and installation data to select the surveillance sites. Sites selected should include the widest range of CCE manufacturers, CCEOP and non-CCEOP equipment, as well as a mix of levels, easy to reach/hard to reach and well performing/low performing areas. Site selection will be in consultation with the national EPI.
- Introduce and train regional and health facility staff on the PMM concept and indicators, reporting tool/templates, data standards, reporting frequency, agree on roles and responsibilities of local government focal points, etc either through individual visits or combined workshops. Ensure that the modality of data collection is appropriate (e.g. use of technology and language) for the country context and staff reporting.
- Develop a routine site visit plan with at least two visits per year to each site, ensuring participation of national EPI technicians/staff whenever possible.

Sentinel Surveillance Officer will be responsible for:

- Compiling monthly data from sentinel sites to submit to national authorities and WHO PQS via the CCIS online tool;
- Carrying out surveillance visits each month to selected sites based on the site visit plan, to improve completeness of inventory and reporting as well as provide support/feedback to health facility staff;
- Carrying out and/or coordinate failure analysis through visits to facility level and submit reports to in-country stakeholders and WHO PQS via the CCIS online tool if trigger thresholds for indicators are reached;
- Including the relevant technical national and regional cold chain staff, to the extent possible, in all PMM activities, including site visits and failure analysis;
- Convening key technical EPI cold chain staff every quarter to review the data and CCE performance issues identified and discuss mitigation actions;

Key deliverables and reports:

- Annual workplan of surveillance activities (By the start of data collection, no later than 3 months after the start date of contract);
- Health facility-level data collection and reporting tools adapted to the local context (By the start of data collection, no later than 3 months after the start date of contract);
- Monthly performance reports using the CCIS tool, combining routine health facility reporting, field visit, and failure analysis findings (Monthly from the start of data collection);
- Ad-hoc written failure analysis reports (No later than 4 weeks after failure analysis takes place);
- Up to date CCE inventory for sentinel sites (Update ongoing throughout project).

WORK SCHEDULE

The project duration will be [xx] (including 3 months for set up), full time, starting from [xx]. The Sentinel Surveillance Officer will be based at [xx] with frequent travel to selected health facilities. The officer will primarily report to [xx], but will also be responsible for coordination with designated staff at WHO PQS.

DESIRED QUALIFICATIONS AND SPECIALIZED KNOWLEDGE/EXPERIENCE FOR SURVEILLANCE OFFICER

- Minimum of 5 years of relevant experience in cold chain and vaccine management required with an understanding of temperature monitoring procedures and products a plus;
- Experience with CCE maintenance a plus;
- Understanding of the national EPI system a plus;
- Strong analytical capacities; excellent ability to synthesize information and relate action to results;
- Ability to multi-task and produce quality outputs on short deadlines;
- Excellent communication, presentation, team-work and cooperation skills;
- Excellent command of English language, report writing skills a plus;
- Excellent command of the local language;
- Computer skills, including quantitative analysis and reporting tools;
- Travel up to 50% of the time to selected facilities, as needed, to support training, data collection, and issue investigation.